REMARKS

Claims 1-20 are pending in the Application.

Claims 1, 2, and 19 are currently amended.

No claims have been cancelled.

No claims have been withdrawn.

Claims 1-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Schinitsky et al. ("*Schinitsky*") (U.S. Patent 4,938,969) in view of Murad ("*Murad*") (U.S. Patent 5,804,594), Herstein ("*Herstein*") (U.S. Patent 5,902,591) and Taylor et al. ("*Taylor*") (U.S. Patent 5,308,621). Applicant respectfully traverses the 35 U.S.C. § 103(a) rejections as such rejections pertain to the cited claims. Reconsideration and withdrawal of the rejections are respectfully requested in view of the amendments to the claims and the following remarks.

The Examiner states that *Schinitsky*, *Murad*, *Herstein*, and *Taylor* were discussed in a prior Office Action (Applicant assumes the Examiner is referring to the third Office Action mailed December 3, 2002) and that such discussion has been incorporated into the present Office Action. The Examiner further states that Applicant's arguments have been duly considered, but are deemed unpersuasive. The Examiner also notes that Applicant has argued that the prior art does not teach a pH of above 3.5. However, the Examiner states that *Herstein* (column 2, lines 40-47, and column 10, lines 6-17) teaches that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule. *See* Office Action, page 2.

In order to establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300, 1301 (Bd. Pat. App. & Int. 1993); *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 227 U.S.P.Q. 657 (Fed. Cir. 1985). The legal conclusion of obviousness must be supported by facts. See *Graham v. John Deere & Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966).

Where the legal conclusion is not supported by facts, it cannot stand. *Id.* A rejection based on § 103 clearly must rest on a factual basis, and these facts must be interpreted without hindsight reconstruction of the invention from the prior art. The patentability of an invention is not to be viewed with hindsight or "viewed after the event." *Goodyear Company v. Ray-O-Vac Company*, 321 U.S. 275, 279, 64 S.Ct. 593, 88 L.Ed. 721 (1944). The proper inquiry is whether bringing them together was obvious and not, whether one of ordinary skill, having the invention before him, would find it obvious through hindsight to construct the invention. Accordingly, an Examiner cannot establish obviousness by locating references which describe various aspects of the patent Applicants' invention without also providing objective evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. An Examiner's unsupported opinion is not objective evidence.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure. *See* MPEP § 2143. *See also In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991).

Schinitsky discloses a composition comprising from about 2 to about 20% ascorbic acid, about 1 to about 10% tyrosine, and about 0.5 to about 5% zinc sulfate. *See Schinitsky*, column 2, lines 38-45. Applicant respectfully suggests that *Schinitsky* does not anticipate, disclose, or suggest Applicant's composition as disclosed in Applicant's independent claims 1 and 17 and the claims depending therefrom. Applicant's claim 1 (currently amended) discloses a composition comprising at least about 10% (w/v) ascorbic acid; an aminosugar; and water, wherein the composition has a pH of more than 3.5. In addition, Applicant's claim 17 (previously presented) discloses a composition for treating an inflammatory skin ailment, the composition comprising: at least about 5.0% (w/v) ascorbic acid; at least about 10% (w/v) glucosamine; a non-toxic zinc salt; a tyrosine compound; and water, wherein the composition has a pH of more than 3.5. *See*

Applicant's claims 1 and 17. Applicant respectfully suggests that *Schinitsky* does not disclose or suggest various features of Applicant's claim(s) such as an aminosugar or the composition having a pH of more than 3.5. Applicant further respectfully suggests that the Examiner has erroneously attempted to remedy the deficiencies of *Schinitsky* by combining with three other references, *Murad*, *Herstein*, and *Taylor*, to arrive at Applicant's claimed invention. Applicant also respectfully suggests that the Examiner has not presented any evidence regarding a motivation or suggestion to combine the references to arrive at Applicant's claimed invention.

Murad discloses a composition comprising at least four components: a sugar compound, a primary antioxidant component, at least one amino acid component, and at least one transition metal component. *See Murad*, column 3, lines 25-35. Further, *Murad* prefers an embodiment where the composition is administered orally. In a preferred *Murad* embodiment, the composition is administered as a tablet or capsule having about 1 mg to 2,000 mg of *Murad* composition. *See Murad*, column 4, lines 39-50. Further, *Murad* discloses that although any suitable route of administration may be employed, oral administration is preferred. *See Murad*, column 8, lines 43-52. Further, all three routes of administration of the *Murad* composition disclosed in the *Murad* examples comprise orally administrated forms such as capsules (*Murad* Example 1), soft gelatin capsules (*Murad* Example 2), and tablets (*Murad* Example 3). *See Murad*, column 10, lines 5-32. Further, *Murad* claim 1 discloses an orally administered pharmaceutical composition comprising the following *Murad* components: a sugar compound; a primary antioxidant component; at least one amino acid component; and at least one transition metal component. *See Murad*, claim 1.

Further, *Murad* does not anticipate, disclose or suggest a tyrosine compound and there is no disclosure or suggestion in *Murad* regarding pH. Applicant respectfully suggests that the *Murad* emphasis on oral administration, specifically capsules, soft gelatin capsules, and tablets, teach away from Applicant's composition having a pH of more than 3.5. Applicant also respectfully suggests that since *Murad* is preferably administered orally, pH is not a critical feature of the *Murad* composition and actually teaches away from Applicant's composition.

Applicant respectfully suggests that there is no motivation or suggestion to combine the *Schinitsky* composition comprising ascorbic acid, tyrosine, and zinc sulfate with no disclosure of an aminosugar or pH levels with the specific four-component *Murad* composition preferably

administered orally with no disclosure of tyrosine or pH levels to arrive at Applicant's claimed invention. Applicant respectfully suggests that the Examiner is utilizing *Murad* to erroneously remedy the deficiencies of *Schinitsky* regarding an aminosugar and pH levels. However, *Murad* only discloses the *Murad* sugar compound when utilized in the *Murad* composition that requires at least three additional elements such as the primary antioxidant, at least one amino acid component, and at least one transitional metal component, preferably in an oral form. Applicant also respectfully suggests that there is no reasonable expectation of success of combining *Schinitsky* with *Murad* to arrive at Applicant's claimed invention.

Herstein discloses a composition comprising two phases. The first *Herstein* phase is a powder phase containing ascorbic acid. The second *Herstein* phase is a liquid emulsion phase containing a stabilizing effective amount of an organoclay composition. *See Herstein*, column 2, line 65 - column 3, line 6. *Herstein* discloses in great detail the two phases. *Herstein* discloses that the liquid phase comprises an emulsifier that can be selected from various emulsifiers. *See Herstein*, column 4, line 31 - column 6, line 19. Further, *Herstein* does not anticipate or disclose an aminosugar or tyrosine. Further, *Herstein* discloses various anti-inflammatory agents that can be utilized in the *Herstein* composition that do not suggest an aminosugar and thus, *Herstein* actually teaches away from Applicant's use of an aminosugar. *See Herstein*, column 9, lines 52-64.

Applicant respectfully suggests that there is no motivation or suggestion to combine or modify the *Schinitsky* composition, comprising ascorbic acid, tyrosine, and zinc sulfate, with the *Murad* composition comprising four specific components preferably administered orally with no disclosure or suggestion of tyrosine or pH levels with *Herstein* that requires a two-part system comprising 5% powdered ascorbic acid and a 95% liquid phase that requires the use of the *Herstein* organoclay material.

Applicant respectfully suggests that the Examiner is using improper hindsight to remedy the deficiencies of *Schinitsky* with *Murad* and *Herstein*. The Examiner erroneously attempts to utilize the combination of *Schinitsky*, *Murad*, and *Herstein* to render obvious Applicant's claimed invention. Applicant respectfully suggests that the Examiner is utilizing improper hindsight by selecting features of the various compositions of the various references in an attempt to disclose each of the individual components of Applicant's claimed composition.

The Examiner has attempted to use *Herstein* to teach that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule. *See* Office Action, page 2. Applicant respectfully suggests that the Examiner is using improper hindsight based on Applicant's claimed invention to erroneously interpret *Herstein* regarding pH. *Herstein* discloses that preferably, the pH of the final *Herstein* composition should be maintained within the range of 3.5 to 4.1. *Herstein* further discloses that the pH of the *Herstein* liquid phase is preferably maintained at 8.2 to 8.9 and more preferably 8.6 to 8.9. *Herstein* further discloses that organic ingredients can be emulsified in water along with the *Herstein* organoclay material. To this *Herstein* emulsion can be added the remaining ingredients and finally the pH can be adjusted to the desired level. *Herstein* further discloses that while the *Herstein* composition can be made generally in any order, it is important that the oil phase of the *Herstein* emulsion be established with the *Herstein* organoclay material therein. *See Herstein*, column 10, lines 6-43.

Applicant respectfully suggests that the *Herstein* disclosure regarding pH is directed to the *Herstein* composition comprising a specific two-phase system that requires a powdered ascorbic acid phase and a liquid phase comprising an emulsion comprising an organoclay material where the liquid phase is preferably maintained at a pH of 8.2 to 8.9. Applicant respectfully suggests that without the use of improper hindsight, *Herstein* cannot render obvious Applicant's features such as a composition having a pH of more than 3.5.

Applicant respectfully suggests that there is no motivation or suggestion to combine or modify the *Schinitsky* composition, comprising ascorbic acid, tyrosine, and zinc sulfate with no disclosure of an aminosugar or pH levels, with the teachings of *Murad* of a composition comprising a sugar compound, a primary antioxidant component, at least one amino acid component, and at least one transition metal component, preferably administered orally with no disclosure or suggestion of tyrosine or pH levels, with the specific *Herstein* two-phase system comprising a liquid phase of an emulsion requiring an organoclay material that is maintained at a pH of 8.2 to 8.9, that only upon mixture of the two *Herstein* phases does the final pH disclosure become applicable, to render obvious Applicant's claimed invention.

Applicant respectfully suggests that the Examiner then utilizes a third reference, *Taylor*, in addition to *Murad* and *Herstein*, in a further attempt to remedy the deficiencies of *Schinitsky*. *Taylor* discloses a composition comprising a carrier and ascorbic acid in suspension within the

carrier wherein the ascorbic acid comprises fine particles of ascorbic acid predominantly sized below 20 microns. *See Taylor*, column 2, line 67 – column 3, line 64, and claim 1. *Taylor* discloses a process comprising heating a mixture of a pharmaceutically acceptable carrier and the ascorbic acid followed by cooling, under specific *Taylor* conditions, such that the crystals that form on cooling are sufficiently fine to facilitate transdermal diffusion. Preferably, the crystals are predominantly sized less than 20 micrometers in average length of side. *See Taylor*, column 2, line 67 - column 3, line 15. Applicant respectfully suggests that *Taylor* requires a very specific process to provide for the *Taylor* ascorbic acid crystals less than 20 micrometers in size. Further, *Taylor* does not anticipate, disclose, or suggest an aminosugar, tyrosine, or pH levels.

Applicant respectfully suggests that the Examiner is utilizing improper hindsight to select various features of the references and combining the references without any motivation or suggestion to arrive at Applicant's claimed invention. Applicant also respectfully suggests that there is no reasonable expectation of success of combining *Schinitsky*, disclosing a composition comprising ascorbic acid, tyrosine, and zinc sulfate, with *Murad*, disclosing a composition comprising a sugar compound, a primary antioxidant component, at least one amino acid component, and at least one transition metal component, preferably administered orally, with the specific *Herstein* two-phase system, one phase of powdered ascorbic acid and the other phase of a specific emulsion comprising an organoclay material with a discussion regarding pH only relating to the specific *Herstein* two-phase system, with the *Taylor* disclosure of a two-part system comprising ascorbic acid crystals of up to 20 micrometers in size to arrive at Applicant's claimed invention. Applicant respectfully suggests that the Examiner is starting with *Schinitsky* and then, using improper hindsight, selecting the various features of Applicant's claimed composition from the various references to arrive at Applicant's composition.

Further, Applicant respectfully suggests that the very specific preparations of the compositions of the references utilized by the Examiner require specific components and specific concentrations prepared in specific ways and there is no indication that there would be any reasonable expectation of success of being able to combine these various referenced components to arrive at Applicant's claimed invention. Applicant respectfully suggests that the references, alone or in combination, do not anticipate, disclose or suggest Applicant's various claim features

such as Applicant's high concentration of ascorbic acid, an aminosugar, and a composition having a pH of more than 3.5.

Further, Applicant respectfully suggests that the individual references disclose specific compositions comprising specific components prepared specific ways due to the synergistic effects that each particular referenced composition provides that prevents the simple combination of the features of the various references to arrive at Applicant's claimed invention.

Applicant also respectfully suggests that the lack of motivation or suggestion to combine the references is further emphasized by the fact that the Examiner has not provided any basis for a motivation or suggestion to combine the references. The Examiner has stated that it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art with the expectation that the combination of said components would effectively treat and reduce wrinkles and increase the stability of the ascorbic acid present within the composition. The Examiner has further stated that therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references. *See* Office Action mailed December 3, 2002, page 4.

Applicant respectfully suggests that the Examiner's general statements do not provide for the specific motivation or suggestion that is required to begin meeting the requirements for establishing a *prima facie* case of obviousness. Applicant respectfully suggests that the Examiner cannot rely on improper hindsight to search through the references to find each individual feature of Applicant's claimed invention and then merely state that such references can be combined to arrive at Applicant's claimed invention with the expectation that the combination of said components would effectively treat and reduce wrinkles and increase the stability of the ascorbic acid present within the composition.

Applicant also respectfully suggests that the presence of a property not possessed by the prior art is evidence of non-obviousness. *See* MPEP § 716.02(a). Applicant respectfully suggests that the results obtained in the treatment of rosacea of two subjects as described in paragraphs 00037 and 00038 at pages 16 and 17 of Applicant's specification and the Figure 4 that is described in paragraph 00039 at page 17 of Applicant's specification provides for example depictions of the cosmetic and therapeutic benefits of Applicant's composition. The results also

demonstrate that Applicant's composition as recited in Applicant's independent claims and the claims depending therefrom have a synergistic effect that results in a composition that is superior to other compositions. Topical use of Applicant's composition by one subject resulted in complete remission of the rosacea. *See* Applicant's Specification, paragraph 00037, bridging pages 16 and 17. Further, Applicant's composition was utilized on a second subject whose complexion showed marked improvement. *See* Applicant's Specification, paragraph 00038, page 17. Figure 4 of Applicant's Specification also discloses the synergistic effects provided by Applicant's composition. *See* Applicant's Specification, paragraph 00039, page 17, and Figure 4.

In conclusion, Applicant respectfully requests that the Amendments to the Claims be entered. Applicant further respectfully requests that this Application be re-examined in light of the above amendments and remarks. Applicant further respectfully requests that the rejections under 35 U.S.C. § 103 be withdrawn and that the claims remaining in the Application be allowed.

No new matter has been added, merely amended to more particularly point out and distinctly claim the subject matter Applicant believes is inventive.

Applicant notes that the Notice of Draftsperson's Patent Drawing Review (PTO-948) has not been received.

Since new claims have not been added, no additional filing fees are believed to be due. However, the Commissioner is hereby authorized to charge any fees or credit any overpayment to Deposit Account Number 23-2426 of WINSTEAD SECHREST & MINICK P.C. (referencing number 41758-P001P2X1).

If the Examiner has any questions or comments concerning this paper or the present application in general, the Examiner is invited to call the undersigned at (214) 745-5710.

Respectfully submitted,
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